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EXAMINER	
SALZMAN, KOURTNEY R	
ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,187	BAE ET AL.	
	Examiner	Art Unit	
	KOURTNEY R. SALZMAN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 18, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *October 20, 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed July 18, 2008 has been entered and fully considered.

2. Claims 1-3 remain pending in the application.

3. Claims 4-9 have been added and fully considered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over NANKAI et al (US 5,120,420), in view of IKETAKI et al (US 6,576,117).

Regarding claim 1, NANKAI et al teaches the application of a current or voltage to a working electrode where the reading level is the concentration of the interest. (c. 5, l. 46-53) NANKAI et al teaches a biosensor comprising multiple measuring electrodes, shown in figure 13 as reference numbers 41-42, functioning as working electrodes. The concentrations read by the electrodes are averaged for a mean value. (c. 8, l. 42-45)

NANKAI et al fails to teach the use of applying the voltage current to the electrodes multiple times sequentially.

IKETAKI et al teaches a method for using an electrochemical sensor through application of voltage to an electrode twice consecutively, as shown in figure 1. As shown in figure 2, reference box 2, the output parameters of the sensor, or in the case of the instant application the parameters as measured as the average of the sensor reading is analyzed and can be reported without correction or as an off-value.

At the time of invention, it would have been obvious to one of ordinary skill in the art to perform the readings of the two electrode system as disclosed in NANKAI et al, two times, as shown in IKETAKI et al because both apparatus use multiple

either electrodes or runs to minimize error, in turn, providing a measurement with higher accuracy (NANKAI et al c.8, l. 42-45 and IKETAKI et al c. 3, l. 2-4)

Regarding claim 2, NANKAI et al teaches the delivery of a pulse and monitoring for time between when a sample is delivered and when the detector notices differences in voltage. (c. 11, l. 16-26) Therefore, if the sample is never detected (in that the sensor never reads a voltage difference) it is obvious that the sensor worked in error.

Regarding claim 6, IKETAKI et al shows the incubation time to be the time between t1 and t2 where the circuit is open, as shown in figure 1.

Regarding claim 7, NANKAI et al teaches in example 5, column 9, lines 31-47, for the electrode system outputs to be monitored extensively and compared.

Regarding claim 8, in conjunction with the previous rejection of claim 2, it would be obvious to monitor the amount of time necessary for the sensor to read the sample because if no reading is being made follow an excessive amount of time, presumably outside the predetermined critical range, the sample or sensor is functioning in error or not functioning at all.

7. Claim 3 and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over BEATY et al(US 6,645,368), in view of NANKAI et al (US 5,120,420) and IKETAKI et al (US 6,576,117).

BEATY et al teaches a sensor and method of using the sensor which employs amplifiers and switches to measure biological material. The noninverting (+) terminal, or input of the operational amplifier connects to a power supply as stated in c. 8, l. 46-48. The inverting (–) terminal, or output of the operational amplifier connects to multiple switches or terminal (c. 8, l. 32-38) which output "DC excitation" “across the biosensor". (c. 8, l. 36-38) The microprocessor, or instrument 32 of BEATY et al, more specifically the microprocessor unit inside the instrument 54, is connected to the circuit of switches of 36, as shown in figure 2. The microprocessor is equipped to handle the calculations of concentrations of components with corrections (c. 8, l. 15-30) and extensive equations including those shown in column 9, line 35-column 10, line 10. BEATY et al describes the process of measuring concentrations using the apparatus described in column 10, lines 49. BEATY et al states the instrument 32 contains a display for the communication of a result in column 10, line 46-48.

While the microprocessor of BEATY et al is capable of calculating complicated functions, it does not explicitly state the use of the microprocessor to average readings from multiple electrodes or the use of multiple pulses.

Regarding claim 1, NANKAI et al teaches the application of a current or voltage to a working electrode where the reading level is the concentration of the interest. (c. 5, l. 46-53) NANKAI et al teaches a biosensor comprising multiple measuring electrodes, shown in figure 13 as reference numbers 41-42, functioning as working electrodes. The concentrations read by the electrodes are averaged for a mean value. (c. 8, l. 42-45)

NANKAI et al fails to teach the use of applying the voltage current to the electrodes multiple times sequentially.

IKETAKI et al teaches a method for using an electrochemical sensor through application of voltage to an electrode twice consecutively, as shown in figure 1. As shown in figure 2, reference box 2, the output parameters of the sensor, or in the case of the instant application the parameters as measured as the average of the sensor reading is analyzed and can be reported without correction or as an off-value.

It would be obvious to one of ordinary skill in the art to use the analyzing apparatus of BEATY et al to perform the method disclosed by NANKAI et al and IKETAKI et al because BEATY et al recognizes that just the use of an appropriate biosensor is not enough for a completely accurate reading, but instead the combination of the electronic analysis method and the accurate

sensor. (c. 5, l. 44-48) Also, BEATY et al uses simply the generic term biosensor, making it an obvious step to apply the electrical analysis disclosed to the biosensor as described by NANKAI et al and IKETAKI et al. At the time of invention, it would have been obvious to one of ordinary skill in the art to perform the readings of the two electrode system as disclosed in NANKAI et al, two times, as shown in IKETAKI et al because both apparatus use multiple either electrodes or runs to minimize error, in turn, providing a measurement with higher accuracy (NANKAI et al c.8, l. 42-45 and IKETAKI et al c. 3, l. 2-4)

Regarding claim 9, NANKAI et al teaches in figure 7 the concentration corresponding to the current read as specific to the sensor. The response characteristic unique to each sensor is also discussed in column 5, lines 54-59. This functions as the memory of the sensor.

8. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over NANKAI et al and IKETAKI et al, as applied to claim 1 above, and further in view of BATMAN et al (US 6,635,167).

The combination of NANKAI et al and IKETAKI et al teach all the limitations of claims 1 and 2, but fails to teach the process of checking to see if the sample is inserted properly.

Regarding claims 4 and 5, BATMAN et al teaches in column 21, line 61 - column 22, line 9 and column 22, lines 22-24, the sensor device reads the strip

inserted for the determination of whether the strip is good or bad. If the strip is not inserted properly, the instrument displays an error message as stated in column 22, lines 26-27.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize the process of verifying an accurate sample has been supplied, as in BATMAN et al, to allow the operation of the sensor of NANKAI et al and IKETAKI et al, because if the strip isn't properly inserted, the sensor cannot function properly.

Response to Arguments

9. Applicant argues at the bottom of page 7, the applied references don't teach the reading of concentrations corresponding to the amount of current from memory.

a. NANKAI et al teaches in figure 7 for the current read to correspond to a glucose concentration as specific to the sensor. The response characteristic unique to each sensor is also discussed in column 5, lines 54-59. Since the concentration corresponding to the current applied to the sensor is unique to each sensor, the reading of the corresponding concentration from memory obviously happens and would be required to happen during the functioning of the sensor in order for the sensor to be useful.

10. Applicant argues in the first full paragraph of page 8 of the remarks, the applied references do not teach the "self-checking feature" which "checks whether the concentrations read from memory are within a predetermined critical range to display at

least one of an error message and the calculated average value" for proper biosensor functioning.

a. While the applicant may intend the process of checking to make sure the concentrations fall within a certain "critical range" to calculate error, this is not the feature that is claimed. What is claimed is the method step of checking to see if the concentration is within the critical range then displaying an error message or calculated average, but does not connect this step with the determination of an error.

b. Therefore, applicant admits in the arguments submitted on page 8 that the examiner does teach the feature of checking whether the concentrations are within a predetermined critical range in IKETAKI et al, especially column 4, lines 7-12. While applicant argues the expectation range comparison of IKETAKE et al is for a different purpose than that of the instant application, this is irrelevant to what is claimed.

11. Applicant argues beginning at the top of page 9 of the remarks, the applied references don't teach the application of voltages individually "to determine the reaction times and the amount of current flowing in each electrode, and thereof, to determine whether an error has occurred".

c. While the applicant may intend the first claim to read "individually", the actual claim wording teaches "sequentially supplying the respective working electrodes with power supply voltage". The sequential application of voltage is taught by the combination of NANKAI et al in view of IKETAKI et al. NANKAI et

al teaches the use of multiple electrode pairs as taught in the previous office action submitted and in example 5. Figure 12 of NANKAI et al shows a sample sensor, where the travel time to each electrode would allow for sequential application as the travel time for each electrode is different.

d. While the intent of the claim may be to "determine the reaction times and the amount of current flowing in each electrode, and thereof, to determine whether an error has occurred" this step is not claimed in the application to be directly used in this application, therefore, this argument is irrelevant to the claimed feature.

12. Applicant argues in the second paragraph of page 9, the applied references fail to teach "displaying an error message", as claimed in claim 1 of the instant application.

e. Claim 1 of the instant application does not require the display of an error message, but the final limitation requires the display of at least one of an error message and calculated average value. By stating the limitation in the alternative, the display of the error message is not required.

13. Applicant argues in the second paragraph of page 9, the applied references fail to teach "the displaying of an error message if the calculated concentrations are outside a predetermined range".

f. This is not what is claimed. While it may be the intention of the applicant to compare concentration with a predetermined range then display the error message when the concentration is outside of the range and display the calculated average when the concentration is within the range, this is not what is

claimed. The claim simply required the comparison of the concentration to a predetermined range, then the display of an error message or calculated average value. The claim does not require the displayed message to be a result of the comparison with the predetermined range.

14. Applicant argues beginning on the bottom of page 9, the applied references fail to teach "at least the non-inverting terminal of each operational amplifier is connected to a voltage sources and the inverting terminal of each operational amplifier is connected to a switch".

g. The examiner addresses this required meant in paragraph 6 of the office action previously submitted to the applicant, where column 8, lines 32-38 and 46-48 of BEATY et al are used to teach this limitation. Applicant submits no further argument as to how this limitation is not addressed.

h. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

15. Applicant argues in the paragraph starting on the bottom of page 9, the applied references fail to teach the second and third switches grounding the electrodes of the biosensor or a display that displays at least of reaction results and an error message.

i. The examiner teaches in paragraph 6 of the previous office action that BEATY et al teaches multiple switches connected the electrodes of the sensor in

column 8, lines 32-38. The use of the switches to ground the electrodes is an obvious use of switches which is well known in the art.

j. The examiner teaches the display of a result in paragraph 6 of the previously issued office action in instrument 32 of BEATY et al taught in column 10, lines 46-48. While the intended use of the display is to show either an error message or calculated result, the presence of the display which shows a result from the sensor is sufficient within an apparatus claim.

k. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

krs
11/10/2008